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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,218	07/24/2006	Marie-Noelle Bizot	4-32908A	4236

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,218	BIZOT ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-9,13 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-9,13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

noDETAILED ACTION

The receipt of Information Disclosure Statement dated 9/27/05 was acknowledged in the non-final office action, and the receipt of the copy of each cited foreign patent document; and the non-patent literature publication in the said Information Disclosure Statement that was received on 3/28/2008 is hereby acknowledged.

Claim Rejections - 35 USC § 112

1. Claims 1, 5, 7-9, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "a beverage consisting essentially of apple juice and a mixture consisting essentially of an effective amount of tegaserod". The specification does not support the phrase "consisting essentially of". Applicant should demonstrate where in the specification the phrase is cited. ***This is a new matter rejection.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. In view of amending the claims, the rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn.

2. In view of cancelling the claims, the rejection of claims 2-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn.

3. In view of amending the claims, the rejection of claims 5-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 5, 7-9, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE BRUIJN et al. WO0010526 (De Bruijn) in view of Patel et al. US 20030180352 (Patel) and further in view of Achong et al. US 20040162273 (Achong).

De Bruijn teaches a pharmaceutical composition, in particular to a composition for administering active agents which are poorly soluble in aqueous media, and/or which are acid sensitive (abstract). The composition comprises tegaserod (pages 5, and 7) or its salt (page 5) and is prepared to have dissolution in water of about 30%-90% in 5 minutes (page 7), this rate reads on the recitation of instant claim 4. The reference also discloses a dissolution rate of 95% - 100% in 30 minutes (page 8), the rate is close to the recitation of instant claims 2 and 3. Note that using "about" makes the rates probably closer. In addition, it is expected that people skilled in the art are able to adjust dissolution rates by changing different ingredients in a dosage form. The composition could be in the form of tablets or capsules, or parenterally, e. g., in the form of injectable solutions or suspensions or in a suppository form (page 13). The compositions of the invention were packed in conventional manner to keep out humidity, e.g., in a blister pack, optionally with a desiccant (page 17). Regarding claims 8 and 9 that recite amount of tegaserod in the dosage form an amount of 6 mg or 2 mg. De Bruijn teaches that a tablet may have different amounts according to the condition it is used for, for example for irritable bower syndrome (IBS), 1 mg to 12 mg of active agent is used in the tablet (page 9).
Claims 5-9 recited "a crushed tablet" which reads on a chewable tablet, powder, granulate, bead etc. comprising the tegaserod.

De Bruijn does not teach a crushed tablet or beverage.

Patel teaches solid carriers for improved delivery of active ingredients in pharmaceutical compositions. The composition is meant to mask the taste of unpalatable pharmaceutical active ingredients [0028]. Patel suggests agents of the unpalatable drugs among which is tegaserod [0058] and the dosage form can be a powder or a multiparticulate, such as a granule, a pellet, a bead, a spherule, a beadlet, a microcapsule, a millisphere, a nanocapsule, a nanosphere, a micro sphere, a platelet, a minitablet, a tablet or a capsule [0229]. The composition of the

invention can be administered as a chewable tablet, a quick or fast dissolving tablet, an effervescent tablet, a buccal or sublingual solid, a granule, a film, a sprinkle, a pellet, a bead, a pill, a powder, a triturate, a platelet, a strip or a sachet. Compositions can also be administered as" dry syrup", where the finished dosage form is placed directly on the tongue and swallowed or followed with a drink or beverage ([0272], see also claims 24 and 47). The use of water as a beverage is conventional type of a beverage that is usually known and used by the public.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Patel to De Bruijn because Patel teaches a way for masking the unpleasant taste for the drugs disclosed.

Neither of the references disclosed apple juice as a beverage with the tegaserod.

Achong teaches powder pharmaceutical composition. The reference discloses that powder pharmaceutical compositions can also be formulated to contain aesthetically pleasing flavor and sweetener ingredients [0008]. When the powder pharmaceutical compositions can be dissolved in a liquid, such as cold water, ice tea, orange juice, grape juice, and apple juice [0028].

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Achong to the invention of De Bruijn and Patel and use apple juice as Achong teaches because the reference discloses that apple juice is an aesthetically pleasing flavor. The expected result would be a composition comprising tegaserod or a pharmaceutically acceptable salt swallowed by the use of a beverage or added to a beverage such as water or apple juice.

Applicant amended the claims to recite "a beverage consisting essentially of apple juice and a mixture consisting essentially of an effective amount of tegaserod". It is noted that the transitional phrase "consisting essentially of limits the scope of a claim to the specified materials

or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52,190 USPQ 461, 463 (CCPA 1976) (emphasis in original). If the applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061,1063-64 (Bd. Pat. App. & Inter. 1989.

Response to Arguments

2. Applicant's arguments filed 3/28/2008 have been fully considered but they are not persuasive. Applicant argues that:

- Neither DeBruijn nor Patel teach, suggest, or provide motivation to use a crushed tablet of tegaserod, or apple juice as a beverage as recited in Applicant's Claims 1 and 15. The use of crushed tablets of tegaserod containing a known and fixed amount of active ingredient which is not disclosed or suggested in either DeBruijn or Patel is an alternative method of tegaserod administration which is especially suitable for a patient's use at home.

To respond: Applicant is arguing an alternative method of administration of tegaserod which is especially suitable for a patient's use at home. However, instant claims are not directed to a method of administering the drug. The claims are directed towards an oral suspension comprising a beverage consisting essentially of apple juice and a mixture consisting essentially of an effective amount of tegaserod or acceptable salt in the form of at least one of a powder, a .granulate, a .grind, and a pulver of particles. DeBruijn's teaches that tegaserod could be prepared in the form of a suspension (page 13), and that the composition is granulated and sieved (see example 1), Patel teaches a crushed tablet of a drug such as tegaserod is

suspended in a beverage. Achong teaches that powder pharmaceutical compositions can be dissolved in a liquid such as water, milk, orange juice, grape juice, and apple juice

- It has also found that while tegaserod can be administered in a crushed tablet form in various media, apple juice has an unexpected advantage, and superior dissolution profile when compared to other masking agents such as orange juice and apple sauce. See Carrier et al. "Stability and Compatibility of Tesgaserod from Crushed Tablets Mixed in Beverages and Food' American Society of Health-System Pharmacists, Inc. (2004), Pages 1138 (3d column), 1140 (3d column), and 1141 (middle column). Applicant also argues that Achong had no teaching, suggestion or motivation to use the superior dissolution properties of crushed tablets of tegaserod in apple juice and that the reference did not recognized that apple juice is preferable to a host of other aesthetically pleasing flavor and sweetener ingredients. So the combination of DeBruijn, Patel and Achong does not allow for predictable use of the superior dissolution properties of crushed tablet in apple juice.

To respond: Instant claims do not recite the alleged superiority of dissolution profile of tegaserod. In addition, it is noted that It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose from a finite number of predictable pharmaceutically acceptable taste masking beverages such as those disclosed by Achong since the claim would have been obvious because a person of ordinary skill has good reason to pursue the known options within his technical grasp. Since this leads to the anticipated success, it is likely the result is not of innovation but of ordinary skill and common sense. The skilled artisan would have good expectation of producing an oral suspension of tegaserod composition which has a taste masked properties. Finally, the attached document (Exhibit A) was carefully reviewed, however, although it shows that tegaserod can be administered in crushed tablet form in various media and that apple juice appears to be the best, it is noted that the other

acceptable media such as orange juice and water were within the disclosure of Achong. Thus the document demonstrates that such beverages are conventional for a person of ordinary skill in the art to try.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618